IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

VIRGINIA C. DICK,	:	
	:	**Civil No. 1:05-cv-2384**
Plaintiff	:	
	:	
v.	:	**(Chief Judge Kane)**
	:	
AMERICAN HOME PRODUCTS CORP., and WYETH-AYERST LABORATORIES, INC.,	:	
	:	
Defendants	:	

MEMORANDUM

Pending before the Court is Defendant Wyeth's motion for summary judgment on Plaintiff's claims.[1] Upon due consideration, the motion will be granted because Plaintiff has failed to adduce sufficient evidence to support her claims that one of Defendant's products – specifically, a prescription arthritis medication allegedly contaminated with a selective beta blocker – caused her late husband to suffer adverse health effects and premature death. The Court's reasoning is discussed below.

[1] Wyeth was formerly known as American Home Products Corp. Wyeth appears in this action as the sole defendant, on behalf of itself and the unincorporated Wyeth Pharmaceuticals Division of Wyeth, which was improperly named in the complaint as Wyeth-Ayerst Laboratories, Inc.

I. BACKGROUND[2]

Charles M. Dick, a long-time banker who resided in Perry County, Pennsylvania, died at approximately 3:00 a.m. on September 13, 2000, when he was 63 years old. No autopsy was performed on Mr. Dick and the death certificate issued on September 25, 2000, identified coronary artery disease as the cause of death.

During his lifetime, Mr. Dick suffered from several illnesses or ailments. Mr. Dick was diagnosed with rheumatoid arthritis in 1973. Approximately 20 years later, Mr. Dick was also diagnosed with Parkinson's disease, and treated for this condition with family doctors and specialists. In addition to his arthritis and Parkinson's disease, Mr. Dick suffered a significant anterior wall myocardial infarction in 1992, which permanently impaired his heart function. In 1999, Mr. Dick suffered a subsequent sub-endocardial infarction. An x-ray taken shortly before his death revealed that Mr. Dick was also suffering from mild emphysema, and his medical file notes that he had a history of sleep apnea.

From his diagnosis in 1973 until his death, Mr. Dick treated for his rheumatoid arthritis

---

[2] Defendant filed a statement of undisputed facts in support of its motion for summary judgment, and has referred to and produced evidence in support of its statement. (Doc. No. 31.) Plaintiff failed to submit an answer to Defendant's statement of undisputed facts, which is required filing under Local Rule 56.1. See LR 56.1 ("Statements of material facts in support of, or in opposition to, a motion shall include references to the parts of the record that support the statements."). The failure to file a counterstatement is not merely disregard of a technical procedural rule; the absence of a counterstatement with supporting evidence substantially undermines Plaintiff's opposition to Defendant's properly supported motion, and particularly so in this case where Plaintiff failed to support her claims with evidence. Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986) (non-moving party may not rest on allegations in the complaint but must "go beyond the pleadings and by [his] own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial"). The Court has engaged in an independent review of the record. Where Plaintiff has offered mere argument or no evidence in support of Plaintiff's denial of a fact alleged in Defendant's properly supported statement, the Court has accepted the fact as true. See id.

with Dr. Alan D. Roumm of Camp Hill, Pennsylvania. As part of this treatment, Dr. Roumm prescribed the drug etodolac and Mr. Dick took this medication for a number of years prior to his death. Etodolac is the generic form of the brand-name drug Lodine, and is a non-steroidal anti-inflammatory drug used to relieve pain, tenderness, swelling and stiffness that is caused by rheumatoid arthritis. (Compl.¶ 3; Def. Statement of Material Facts, ¶ 4.) Records show that Merck-Medco, a mail-order pharmacy, filled a prescription for etodolac 300 mg capsules for Mr. Dick on or about July 19, 2000. (Def. Statement of Material Facts ¶ 6 and Ex. 3.)

Approximately three weeks after Mr. Dick's death, on October 5, 2000, ESI Lederle – a generic drug maker owned by Wyeth at that time – issued a notice informing customers that it was voluntarily recalling Lot Number 9991052 of etodolac 300 mg capsules after the company discovered that some capsules from the lot contained variable and unknown amounts of acebutolol, a selective beta blocker that can be used to lower heart rate or blood pressure in order to treat hypertension, congestive heart failure, and ventricular arrhythmia. The recall letter, which was sent to Dr. Roumm, stated that Lot No. 9991052 began being manufactured in September 1999 and product from this lot was delivered to wholesalers, health care professionals, and pharmacies between October 18, 1999, and August 31, 2000.

On May 31, 2005, Mr. Dick's widow and the trustee of his estate, Virginia C. Dick, sued Wyeth in the Perry County Court of Common Pleas, asserting claims for products liability and breach of warranty predicated on her allegations that Mr. Dick consumed acebutolol-contaminated etodolac capsules and that the contaminant caused his health to worsen and ultimately led to his death. In particular, Plaintiff alleges that Mr. Dick suffered from hypotension, or low blood pressure, and that Mr. Dick began experiencing episodic shortness of

breath and fatigue during July, August, and September 2000, and that these episodes increased in frequency and severity over the time that Mr. Dick ingested etodolac in 2000. Plaintiff avers that Mr. Dick's alleged ingestion of Defendant's acebutolol-contaminated etodolac capsules caused him to suffer these adverse health conditions and eventually caused his death.

On November 16, 2005, Wyeth removed the action to this Court pursuant to 28 U.S.C. § 1441 on the basis of diversity jurisdiction. Following discovery, Wyeth moved for summary judgment on all of Plaintiff's claims and the Court subsequently stayed the action pending resolution of Wyeth's dispositive motion.

II. STANDARD OF REVIEW

Summary judgment is proper where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56; White v. Westinghouse Elec. Co., 862 F.2d 56, 59 (3d Cir. 1988). A factual dispute is material if it might affect the outcome of the suit under the applicable law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A factual dispute is genuine only if there is a sufficient evidentiary basis that would allow a reasonable fact finder to return a verdict for the non-moving party. Id. at 249. The evidence presented must be viewed in the light most favorable to the non-moving party. Id. The inquiry is whether the evidence presents a sufficient disagreement to require submission to the jury or whether it is so one-sided that one party must prevail as a matter of law. Id. at 251-52.

The moving party has the initial burden of identifying evidence that it believes shows an absence of a genuine issue of material fact. Childers v. Joseph, 842 F.2d 689, 694 (3d Cir.

1988). Once the moving party has shown that there is an absence of evidence to support the non-moving party's claims, the nonmoving party may not simply sit back and rest on the allegations in the complaint. Instead, the nonmoving party must "go beyond the pleadings and by [its] own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial." Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986) (internal quotations omitted). The evidence must be viewed in the light most favorable to the nonmovant. See Groman v. Township of Manalapan, 47 F.3d 628, 633 (3d Cir. 1995). Summary judgment should be granted where a party "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden at trial." Celotex, 477 U.S. at 322.

With respect to the sufficiency of the evidence that the nonmoving party must provide, a court should grant summary judgment where the nonmovant's evidence is merely colorable, conclusory or speculative. Anderson, 477 U.S. at 249-50. There must be more than a scintilla of evidence supporting the nonmoving party and more than some metaphysical doubt as to the material facts. Id. at 252; Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986).

III. DISCUSSION

In order to prevail on her claims in this case, Plaintiff is required to prove both (1) Defendant's product in question was defective in some way and (2) that the defect was a substantial factor in causing the alleged injury. Spino v. John S. Tilley Ladder Co., 696 A.2d 1169, 1172 (Pa. 1997). Where a plaintiff fails to come forward with evidence to demonstrate that the defendant's products caused plaintiff's injuries, summary judgment in favor of the

defendant is appropriate. See Eckenrod v. GAF Corp., 544 A.2d 50, 52 (Pa. Super. Ct. 1988) ("Summary judgment is proper when the plaintiff has failed to establish that the defendants' products were the cause of plaintiff's injury."); see also Bushless v. GAF Corp., 585 A.2d 496, 499 (Pa. Super. Ct. 1990) ("In order for liability to attach in a products liability suit, a plaintiff must establish that the injuries were caused by a product of the particular manufacturer . . . ."). The Pennsylvania Supreme Court explained the burden as follows:

> [I]t is well established that proof of injury alone, without more, or of the existence of the negligent condition without showing that it caused the injury complained of, is insufficient to establish a case of liability. Proving that an accident happened, or the existence of an opportunity for it to happen in the manner alleged, is entirely insufficient to establish negligence. Plaintiff must go further and show not only defendant's negligence, but that the injuries complained of were the result of such negligence.

Ucci v. Keane, 167 A.2d 147, 150 (Pa. 1961) (internal quotations and citations omitted); see also Sherk v. Daisy-Heddon, 450 A.2d 615, 617 (Pa. 1982) ("Liability in negligence or strict liability is not imposed upon a manufacturer simply for the manufacture of a defective product. Rather, the plaintiff must demonstrate that the injuries sustained were proximately caused by the product's defect.").

In this case, it is undisputed that the last etodolac prescription Mr. Dick received was filled with a product that Wyeth encapsulated. It also appears undisputed that some quantity of etodolac capsules from Lot No. 9991052 were contaminated with variable amounts of acebutolol. However, as Defendant emphasizes, and as borne out by the evidence developed by the parties, there is no evidence to support Plaintiff's claim that Mr. Dick actually received or ingested any capsules that may have come from this lot. Even more fundamentally, there is no evidence to

show that any etodolac capsules Mr. Dick did ingest – whether from Lot No. 9991052 or otherwise – actually contained any acebutolol, much less a quantity of acebutolol sufficient to cause him to suffer adverse health effects or cause his death. Neither Mr. Dick's pharmacy records nor the label on the bottle containing Mr. Dick's July 19, 2000 etodolac prescription indicate that the prescription was filled with capsules from Lot No. 9991052.

In the absence of such evidence, in an effort to prove that her husband received capsules from Lot No. 9991052 Plaintiff relies primarily on the recall letter that ESI-Lederle sent in October 2000. Although the Court is sensitive to the difficulty that Plaintiff may have had to prove through direct evidence that her husband's medication was filled from the contaminated lot, the Court cannot ignore the fundamental requirement that Plaintiff produce at least sufficient circumstantial evidence in order to prove product identification. In this case, Plaintiff's reliance on a single recall letter is insufficient to satisfy this burden, particularly where nothing in the recall letter indicates that Mr. Dick's prescription was or even likely was filled from the contaminated lot. For the same reason, the Court rejects Plaintiff's assertion that the capsules "must be presumed to be from the contaminated lot" simply because a recall letter issued as a precautionary measure. (Doc. No. 33, at 1.) Plaintiff cites no legal authority in support of this contention and the Court finds it unpersuasive.

In her brief in opposition to Defendant's motion, Plaintiff points out that the capsules remaining in her husband's prescription bottle bear the trade dress and markings that are listed in the recall letter and argues that this fact should be sufficient to show that her husband received

and ingested contaminated etodolac capsules from Lot No. 9991052.[3] However, the uncontroverted evidence demonstrates that the markings in question only identify the capsules as 300 mg etodolac capsules by labeling the capsules with the drug dosage and the National Drug Code assigned to the medication. (See Affidavit of Joseph M. DeVito, Doc. No. 38, Ex. A, ¶ 9.) Accordingly, the Court finds that the evidence Plaintiff relies upon is simply insufficient to create an issue of fact over whether Mr. Dick received a prescription that was filled with etodolac from a contaminated lot, or that he ingested any defective capsules from Lot No. 9991052.[4] For this reason alone the Court finds that Defendant is entitled to summary judgment in its favor because Plaintiff would be incapable of prevailing at trial in the absence of evidence to show that Mr. Dick ingested contaminated etodolac capsules from the affected lot.[5]

In addition, review of the record makes clear that Plaintiff has failed to produce any expert testimony that Mr. Dick's alleged consumption of contaminated etodolac capsules actually

---

[3] The recall letter states that "[t]he ESI Lederle 300mg Etodolac Capsule is a white capsule marked with a '300' on one end and '59911' over '3507' on the other end."

[4] The Court's finding is strengthened by evidence in the expert report of Dr. Alan Leff in which he explains that fewer that 30% of the pails of etodolac 300 mg capsules produced from Lot No. 9991052 had the potential to contain any acebutolol at all. The fact that more than 70% of the pails produced did not contain acebutolol further erodes the evidentiary value that Plaintiff places on the Merck-Medco recall letter in order to prove that her husband received contaminated capsules.

[5] In her brief in opposition, Plaintiff also argues that "no evidence rules out the possibility that the capsules ingested by Charles Dick prior to his death contained acebutolol." (Doc. No. 33, at 2.) Whether or not this is true, it is irrelevant and misapprehends Plaintiff's burden in this case. As explained above, Plaintiff bears the affirmative burden of proving that Mr. Dick did receive etodolac capsules from the contaminated lot, that he ingested the drug, and that the contaminated capsules caused him to suffer injury and death. In order to survive summary judgment, Plaintiff had the burden of pointing to some facts in the record to create a triable issue of material fact. She has not done so.

caused or contributed to his injuries or death, and this provides a second reason that Defendant's motion must be granted.[6] In Pennsylvania, unless there is a manifest and obvious relationship between the alleged injury and breach, a plaintiff must produce expert medical testimony in order to prove that an allegedly defective product caused medical injury. See, e.g., Hamil v. Bashline, 392 A.2d 1280, 1285 (Pa. 1978); Albert v. Alter, 381 A.2d 459, 470 (Pa. Super. Ct. 1977).[7] Following review of the allegations and evidence, the Court finds no clear or obvious link between Mr. Dick's alleged consumption of acebutolol-contaminated etodolac capsules and his alleged injuries and ultimate death. Accordingly, it was incumbent upon Plaintiff to come

---

[6] As noted, the Court has already found that Plaintiff produced insufficient evidence to show that Mr. Dick did, in fact, receive etodolac from Lot No. 9991052, or that the capsules he did receive and consume actually contained a quantity of acebutol-contaminated etodolac.

[7] The Pennsylvania Supreme Court explained the reason for this requirement at length in Hamil:

> Normally a plaintiff may establish his case of causation with any evidence, direct or circumstantial, which tends to show defendant's actions as the legal cause of his harm. Where, however, the ultimate determinations lie beyond the knowledge or expertise of the average layperson, expert testimony is permitted (and sometimes required) to aid the jury in its understanding of the factors involved and the teaching of the pertinent discipline with respect thereto. Although in certain situations involving physical injury, it is possible for a jury reasonably to infer causation from the circumstances of an accident or occurrence, it is generally acknowledged that the complexities of the human body place questions as to the cause of pain or injury beyond the knowledge of the average layperson. For a plaintiff to make out his cause of action in such a case, therefore, the law requires that expert medical testimony be employed. In addition to its bearing on whether or not the defendant's conduct was negligent, such testimony is needed to establish that the injury in question did, with a reasonable degree of medical certainty, stem from the negligent act alleged.

Hamil, 392 A.2d at 1285 (internal citations omitted).

forward with sufficient expert testimony to prove her claims that Mr. Dick's alleged injuries and subsequent death were caused by ingestion of contaminated etodolac. Rather than doing so, Plaintiff elected to rely on selections of deposition testimony given by Mr. Dick's treating physicians in lieu of obtaining testimony from a qualified expert. (See Def. Statement of Material Facts, Ex. 10, Letter from Jerry Philpott, Esq., to Melissa A. Wojtylak, Esq., dated December 20, 2006).[8] Plaintiff has identified no case law to support her position that she can substitute deposition testimony from fact witnesses in the place of valid expert testimony for purposes of creating an issue of material fact regarding the role acebutolol allegedly played in causing or contributing to Mr. Dick's death.

Moreover, even if the testimony of Mr. Dick's treating physicians were an acceptable substitute for qualified expert opinion testimony, none of these witnesses actually testified to a reasonable medical certainty that acebutolol-contaminated etodolac capsules caused or contributed to Mr. Dick's alleged injuries. At most, these treating physicians testified that if Mr. Dick ingested acebutolol, then it would be possible that the ingestion of the drug "could have" contributed to his death. (Def. Statement of Material Fact, Ex. 2, Dep. of Dr. Alan D. Roumm, M.D., at p. 49; Ex. 6, Dep. of Dr. Barbara K. O'Connell, M.D., at p. 58.)

Dr. O'Connell conceded that she had "no idea" whether Mr. Dick ever consumed an acebutolol-contaminated etodolac capsule. (Id.) For his part, both Dr. Roumm's speculative testimony that he had "concerns that [acebutolol] could have contributed to [Mr. Dick's] death" and that he believed aceubutolol was a "significant factor" in Mr. Dick's death are predicated

[8] Specifically, the letter states that "[t]he Plaintiff will rely only on the depositions of the treating physicians for purposes of opinions that would ordinarily be expected to be in the form of expert reports."

upon assumptions that have been shown to be erroneous and without an adequate factual basis. (Id.) Dr. Roumm acknowledged that the basis for his testimony is the fact that Mr. Dick was prescribed etodolac and that "the lot numbers he received were the same lot numbers as the contaminated drug." (Id.) But this assumption is unfounded because there is no evidence that Mr. Dick actually received etodolac capsules from Lot No. 9991052, or even that if Mr. Dick did receive etodolac capsules from this lot that they were contaminated with acebutolol. Thus, even if the testimony from Dr. O'Connell and Dr. Roumm could qualify as the expert testimony Plaintiff is required to produce in order to prevail on her claims, it could not satisfy her burden of proof because the testimony of each witness lacks a sufficient evidentiary basis. See, e.g., Summers v. Certaineed Corp., 886 A.2d 240, 244 (Pa. Super. Ct. 2005) ("For a plaintiff to survive summary judgment, the conclusion by the expert has to be supported by the record.").

In contrast to the foregoing, Defendant has submitted expert reports by Drs. Alan Leff, M.D., and Daniel Edmundowicz, M.D. Dr. Leff is board-certified in pharmacology and Dr. Edmundowicz is a board-certified cardiologist. As reflected in their reports, Drs. Leff and Edmundowicz consulted scientific literature and reviewed Plaintiff's medical history and the testimony of Mr. Dick's four treating physicians, and both experts opined to a reasonable degree of medical certainty that Mr. Dick's medical symptoms in 2000 and his death in September 2000 were not attributable to ingestion of acebutolol. (Def. Statement of Material Facts, Exs. 12, 13.) Plaintiff has no expert witness capable of refuting the scientific conclusions that Defendant's experts were prepared to give at trial.

Because Plaintiff has failed to present evidence sufficient to prove medical causation as required under Pennsylvania law, Defendant is entitled to summary judgment on Plaintiff's

claims.

IV. CONCLUSION

For the reasons set forth above, the Court finds that Defendants have demonstrated an absence of evidence in support of Plaintiff's claims, and the Court finds further that Plaintiff has failed to identify evidence sufficient to show both (1) that Mr. Dick received and ingested acebutolol-contaminated etodolac capsules from Lot No. 9991052 and (2) that Mr. Dick's alleged consumption of Defendant's pharmaceutical products caused or contributed to his alleged injuries and eventual death. Accordingly, Defendant's motion for summary judgment will be granted. An order consistent with this memorandum follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

VIRGINIA C. DICK,	:	
	:	**Civil No. 1:05-cv-2384**
Plaintiff	:	
	:	
v.	:	**(Chief Judge Kane)**
	:	
AMERICAN HOME PRODUCTS CORP., and WYETH-AYERST LABORATORIES, INC.,	:	
	:	
Defendants	:	

ORDER

AND NOW, this 2nd day of June 2009, upon consideration of Defendant's motion for summary judgment (Doc. No. 30), and for the reasons set forth in the attached memorandum, IT IS HEREBY ORDERED THAT the motion is GRANTED. The Clerk of Court is directed to enter judgment in favor of Defendant on Plaintiff's claims and to close the file.

/s/ Yvette Kane
Yvette Kane, Chief Judge
United States District Court
Middle District of Pennsylvania